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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/816,183

03/31/2004

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EXAMINER

VU, QUYNH-NHU HOANG

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/816,183	Applicant(s) FEITH ET AL.	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 8, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 7, 8, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Response to Amendment

Amendment and Request for Continued Examination (RCE) filed on 2/24/09 have been entered.

Claims 1-3 are present for examination.

Claims 7-8, 20-21 are withdrawn.

Claims 4-6, 9-19 and 22-23 are cancelled.

Applicant's arguments filed on 2/28/09 have been fully considered but are not persuasive.

Therefore, claims 1-3 are rejected over the same grounds of rejection as set forth in the office action mailed 11/24/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. No where in the Specification discloses that a first pressure resulting from fluid in the flow channel; a third pressure resulting from fluid in the injection lumen greater than one of said first pressure and said second pressure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as anticipated by Richmond (US 4,946,448).

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Richmond discloses an injection port comprising: a housing defining a flow channel 80 and having an injection lumen 66 extending in fluid communication with the flow channel;

first portions of the housing defining a first valve seat 78 (Fig. 2 with the solid line);

second portions of the housing defining a second valve seat 82, 83 around the injection lumen (Fig. 2 with the dash line); a valve element 84 disposed to extend transverse to the injection lumen;

the valve element forming a first seal with the first valve in response to a first pressure (at rest or original state, Fig. 2 with the valve 84 in solid line), the first pressure resulting from fluid in the flow channel (at this point the slit 86 closed condition and the valve 84 has curve-shaped rested on valve seat 78);

the valve element forming a second seal (the valve 84 deformed in different shaped at dash line in Fig. 2 and rest on second valve seat 82, 83). It is inherently that a second pressure resulting from fluid in the flow channel (a force to press down) is greater than the first pressure at original state, therefore, the valve disc 84 is deformed in different shape (dash line), and liquid flows downwardly through the line 34 (Fig. 2 with the dash line, col. 4, lines 37+);

and the valve element 84 forming an open configuration between the lumen and the flow channel in response to third pressure resulting from fluid in the flow channel (Fig. 3). At this point, the pressure at upstream (a third pressure) is largest pressure, therefore, this allow liquid to flow in an upstream direction through the check valve (col. 6, lines 37+).

As noted that, if the third pressure is smaller than the first pressure, the slit 86 will not be opened and the valve 84a stills rest on element 82, 83, and the valve disc 78 still in the shape shown in dash line of Fig. 2 but not sit on valve seat 78 as shown in Fig. 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as obvious over Blomquist et al. (US 4,922,954) in view of Brost (US 3,889,710).

Blomquist discloses, Figs. 6-9, a bi-directional vent/air/valve with a resilient sealing member 38. However, the device of Blomquist is similar to the structure of claimed invention, (as described below for details), therefore, the device of Blomquist is capable of using or applying in fluid stream line. For example, the fluid stream lines can flow in the same direction of the arrows (direction of air flow) showed in Figs. 8-9 under some type of pressures applied.

The device comprising: a housing defining a flow channel 32; and a lumen 31;
a first portion of the housing defining a first valve seat 39;
a second portion of the housing defining a second valve seat 38;
a valve element 37 disposed to extend transverse to the lumen 31;
the valve element 37 forming a first seal with the first valve seat at 39 in response to a first pressure (Fig. 7), the first pressure resulting from air/fluid in the flow channel at equilibrium condition.

a valve element 37 forming a second seal (the valve element 37 in Fig. 8 deformed in different shape with the valve element 37 in Fig. 7) with the second valve seat at seating surface of element 38 in response to a second pressure. At this point, the air/fluid pressures in Fig. 8 called second pressure must be larger than the first pressure and causes the valve element 37 deformed and located in different location compares with location of valve element 37 seat in Fig. 7. Since then, the air/fluid can flow into the chamber 32 (see arrow direction in Fig. 8).

and valve element 37 forming an open configuration between the lumen and the flow channel in response to a third pressure (Fig. 9). At this point, it is inherently that the third pressure/negative pressure must be greater than one of the first pressure and the second pressure, therefore, the vent/fluid flow out in Fig. 9 and opposites direction with vent air/fluid flow in Fig. 8.

Blomquist disclose the flow lumen but does not show the flow lumen extending as claimed invention.

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Brost discloses an injection port comprising a housing defining a flow channel 26 and an injection lumen 22 extending in fluid communication with the flow channel.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Blomquist with a flow lumen or injection lumen extending, as taught by Brost, in order to provide the fluid communication with other device.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5-7 of U.S. Patent Nos. 6,364,861. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are not structurally distinguishable from the claims in the patents.

For example: the limitation "the valve element forming an opening configuration between said lumen and said flow channel in response to a third pressure in said lumen greater than one of said first pressure and said second pressure" of claimed invention is equivalent of the limitations of claims 5-6 and 7 of US 6,364,861.

Response to Arguments

Applicant's arguments filed 2/24/09 have been fully considered but they are not persuasive.

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Rejection Under 35 U.S.C. 102, Richmond reference (US 4,946,448):

1. Applicant argues that claim 1 requires both that the first and second pressures both result from fluid in the flow channel.

In response, Richmond clearly includes first and second pressures both result from fluid in the flow channel. For example, when fluid gets into the conduit 34 and upper housing 66 at a first pressure, the valve disc 84 remains closed until applied second pressure (greater than first pressure) and causes the valve 84 located in different location (see dash line in Fig. 2).

2. Applicant argues that: Richmond describes element 82 as a series of prongs, and element 83 as the round tips of those prongs. The prongs are not a valve seat as described by the Examiner.

Although Ref Richmond does not explicitly state that elements 82 and 83 are as valve seat, However, labels, statements of intended use, or functional language do not structurally distinguish claims over prior art, which can function in the same manner, be labeled in the same manner or be used in the same manner. See In re Pearson, Ex parte Minks, and In re Swinehart.

In this case, the valve disc 84 in dash line of Fig. 2 rested on elements 82, 83. Therefore, Examiner considers the elements 82, 83 as valve seat.

Rejection under 35 U.S.C 103:

1. Applicant argues that Blomquist never responds to a first pressure by forming a first seal with the valve element disposed against a first valve seat. Blomquist never describes a first and second pressure both resulting from fluid a flow channel. Examiner respectfully disagrees with Applicant. It is noted that, according to Specification of Applicant on pg 13, lines 11- pg 14, line 2 (Figs. 14-16, Elected Species), nowhere clearly discloses on pages 13-14 that a first pressure by forming a first seal with a valve element disposed against a first valve seat. Application only states that : "In its normal state, the port 32 is positioned with the valve element 74 biased to form a first seal with the first valve seat 110 and a second seal with a third valve seat 103 as illustrated in Figure 14" (page 13, lines 18-20). Applicant does not mention any pressure applied in Fig. 14 whatsoever. Applicant only mentioned applying some fluid pressures in Figs. 15-16 but not in Fig. 14 at all. Therefore, with the broadest interpretation,

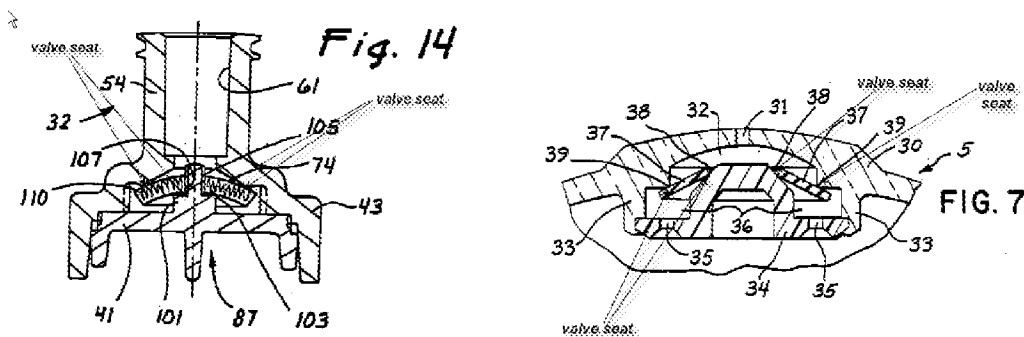
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Examiner interprets that there is no pressure or the pressure under equilibrium at normal state in Fig. 14 and can be called first pressure.

Similarly, Blomquist discloses that the vent air/fluid flow in the equilibrium state or normal state, there is no pressure, in other words, the first pressure = 0 at equilibrium/normal state. At this state, the valve element 37 rested on edge 39 and seating surface 38.

The valve seat locations of Application in Figs. 14 are similarly to the reference of Blomquist.

At normal state:



2. Applicant argues that: nor does Bloomquist describe the valve element forming a second seal with the second valve seat in response to a second pressure, the second pressure resulting from fluid in the flow channel, the second pressure greater than the first pressure of the fluid in the flow channel as is required by claim 1.

In response, Bloomquist clearly shows that: under some pressure, the valve element 37 in Fig. 8 deformed in different shape with the valve element 37 (first seal) in Fig. 7. In response to a second pressure, the valve element 37 in Fig. 8 moved and located on the sealing surface 38 with new location compares with location in Fig. 7. At this point, the air/fluid flow into the chamber 32 by arrow direction showed in Fig. 8. It is inherently that the second pressure must be greater than the first pressure, therefore, the air/fluid can be flowed into the chamber.

Rejection of Double Patenting:

Applicant argues that claims 1-3 require the valve element forming an open configuration between said lumen and said flow channel in response to a third pressure resulting from fluid in the

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injection lumen, the third pressure greater than one of said first pressure and said second pressure. As this limitation is not found in claim 1-25 of the '861 patent.

In response, although the conflicting claims are not identical, they are not patentably distinct from each other because they are not structurally distinguishable from the claims in the patents.

In claims 5-6 of '861 patent discloses a third portions of the housing defining a third valve seat on the side of the valve element opposite the first and second valve seat; and the valve element having properties for forming a third seal with the third valve seat (claim 5); the valve element has properties for opening at least the first seal under the pressure of an injectate in the injection lumen to create a flow path around the valve element between the injection lumen and the flow channel; the valve element has properties for opening the third seal in response a partial vacuum in the injection lumen to aspirate a portion of the fluid in the flow channel around the valve element and into the injection lumen (claim 6).

In other words, the third pressure must greater than first pressure to aspirate or vacuum the fluid in the flow channel.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763